

Application No.: 09/961,091

Case No.: 54404US008

**REMARKS**

Claims 36-60 are pending. Applicants respectfully request reconsideration of the application in view of the following remarks.

**§ 102 Rejections based on U.S. Patent No. 5,632,731 ("Patel")**

Claims 36, 37, 43, 45-47, 49, 51-54, and 58, of which claims 36 and 51 are independent, stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,632,731 ("Patel").

M.P.E.P. § 2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (quoting *Verdegaal Bros. V. Union Oil Co. of California*, 814 F. 2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Applicants submit that Patel cannot anticipate the instant claims because Patel fails to describe, either expressly or inherently, each and every element set forth in the claims.

Specifically, as to claim 36, Patel fails to describe a medical treatment article having at least one microstructure-bearing surface with a plurality of channels, as defined in Applicants' disclosure, therein. Further, Patel fails to describe a medical treatment article that permits transport of fluid between a medical treatment site and a remote area. As to claim 51, the recited method includes use of a medical article having all of the elements and limitations of the article recited in claim 36. Therefore, all of the remarks that follow regarding the patentability of claim 36 apply to claim 51 as well.

The Office Action asserts that the perforated film (12) in Patel corresponds to a fluid control film as defined in Applicants' specification, comprising at least one microstructure-bearing surface with a plurality of channels (perforations 13) therein that permit transport of fluid between [a] medical treatment site (user) and a remote area (16, 17, 18). This is incorrect.

First, the channels in Applicants' disclosure are described as "precisely replicated from a predetermined pattern and form a series of individual open capillary channels that extend *along a major surface*." (page 8, lines 12-14, emphasis added). Patel describes a wound dressing that includes a perforated film. The perforations are not capillary channels that extend along a major surface. Instead, they are merely holes in the film. This is an important distinction functionally.

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The channels recited in the instant claims permit *transport* of fluid between a medical treatment site and a remote area (emphasis added). Throughout Applicants' disclosure, transport is used to convey wicking and/or capillary action (See, e.g., page 5, lines 13; page 8, lines 17-22; page 27, lines 19-21; page 30, lines 22-24) *along a major surface of the fluid control film*. This is in direct contrast to conventional wound dressings such as, for example, those described in Patel, which represent the state of the art that the subject matter of the instant claims is specifically designed to advance (see page 2 line 25 through page 3, line 2). Such dressings (so-called "island dressings" *Id.* and Patel, col. 2, lines 20-21) place an absorbent over the wound itself and do not facilitate wicking and/or capillary action along a major surface of the film. Instead, such dressings only permit diffusion *through* the film. Thus, the channels recited in the instant claims are materially different than the channels described in Patel, and permit fluid transport that is materially different than that described in Patel (controlled wicking and/or capillary action vs. uncontrolled diffusion) and in a different direction than that described in Patel (along a major surface vs. through the film).

Second, Patel fails to describe a medical treatment article that permits transport of fluid between a medical treatment site and a remote area. As used in Applicants' disclosure, the term "remote" refers to a location other than directly over a medical treatment site such as, for example, a wound. Applicants' disclosure specifically distinguishes the "fluid transport to a remote area" feature from dressings such as those described in Patel at page 5, lines 12-15, as follows: "This embodiment functions in an opposite manner to conventional wound dressings that place an absorbent over the wound itself." Patel describes dressings in which the absorbent is placed over the wound (col. 1, lines 56-61 and col. 2, lines 39-42, and Figs. 3-5).

Elsewhere in Applicants' disclosure, the concept of fluid transport to a remote area is characterized as follows:

- "...an optional absorbent may be positioned remote from the wound site, thereby absorbing excess exudate while allowing direct visualization of the wound." (page 5, lines 23-26);
- "The fluid control film of the present invention may transport fluid in any direction suitable to move fluid between the wound site and a remote site on the

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dressing. For example, this may be along the length of a dressing (illustrated in Figs. 1a and 1b), the width of the dressing, may be radially patterned (Fig. 1c), or may incorporate combinations of these flow patterns." (page 31, lines 7-11);

- "The channels in the fluid control film 76 transport fluid from a covered wound site to the absorbent 74. This design illustrates how dressings can be constructed where the absorbent pad is remote from the tissue in the wound site." (page 33, lines 22-24); and
- "If desired, the fluid control film could be extended past the edge of the dressing and the absorbent pad placed remote from the dressing. Also, in place of an absorbent pad it is contemplated that a suction device could be used to transport fluids to or from the wound site." (page 34, lines 6-9).

In each case, Applicants' disclosure consistently describes embodiments that employ the fluid control film to transport fluid to a location other than an absorbent placed over the wound itself – that which is described in Patel and specifically distinguished by Applicants' disclosure. Patel fails to describe anything other than a medical treatment article in which an absorbent is placed over the wound. Thus, Patel fails to describe a medical treatment article that permits transport of fluid between a medical treatment site and a remote area.

Based on Applicants' use of the terms "channels" and "remote", Patel fails to describe a medical treatment article comprising at least one fluid control film component having at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and a remote area. Therefore, Patel cannot anticipate claim 36.

Each of claims 37, 43, 45-47, and 49 depends from claim 36 and is therefore allowable for at least all of the reasons set forth above regarding the allowability of claim 36.

Each of claims 52-54, and 58 depends from claim 51 and is therefore allowable for at least all of the reasons set forth above regarding the allowability of claim 51.

The rejection of claims 36, 37, 43, 45-47, 49, 51-54, and 58 under 35 USC § 102(b) as being anticipated by Patel is improper and should be withdrawn.

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**§ 102 Rejections based on U.S. Patent No. 4,379,454 ("Campbell")**

Claims 51, 55, and 56, of which claim 51 is the only independent claim, stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,379,454 ("Campbell"). Applicants respectfully traverse the rejection. Applicants submit that Campbell cannot anticipate the instant claims because Campbell fails to describe, either expressly or inherently, each and every element set forth in the claims.

The Office Action asserts that Campbell inherently discloses the method recited in claim 51, stating that Campbell describes use of a medical article "comprising at least one fluid control film component (15) having at least one microstructure-bearing surface with a plurality of channels (micropores) (col. 5, lines 15-20) therein that permit transport of fluid between a medical treatment site (user) and a remote area (35),..." The Office Action asserts that the diffusion membrane (15) described in Campbell corresponds to a fluid control film recited in claim 51, and that micropores in the diffusion membrane correspond to the plurality of channels. This interpretation of Campbell is incorrect.

As noted above with respect to Patel, the channels recited in claim 51 are described in Applicants' disclosure as "precisely replicated from a predetermined pattern and form a series of individual open capillary channels that extend *along a major surface*." (page 8, lines 12-14, emphasis added). The passage of Campbell cited in the office action provides no description of *any* microstructured surface, much less the channels recited in claim 51. The Office Action asserts that Campbell discloses micropores that correspond to the channels of Applicants' disclosure. Applicants find no description in the cited passage that could possibly correspond to channels "precisely replicated from a predetermined pattern" forming "a series of individual open capillary channels that extend along a major surface."

Also as noted above with regard to Patel, Campbell fails to describe transport of fluid between a medical treatment site and a remote area. Campbell describes a dosage form that delivers drug and an absorption enhancer to an area of the skin directly covered by the reservoir. As noted above, Applicants' consistently use the term "remote" to refer to a location other than directly over the medical treatment site.

Thus, Campbell fails to describe, either expressly or inherently, each and every element set forth in the claims.

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The rejection of claims 51, 55, and 56 under 35 USC § 102(b) as being anticipated by Campbell is improper and should be withdrawn.

### **§ 103 Rejections**

Claims 39, 42, 44, 50, 59, and 60 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Patel. Claim 57 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Campbell. No secondary references are cited for either rejection under 35 U.S.C. § 103(a).

Applicants submit that the present rejection fails to establish a *prima facie* case of obviousness. § 706.02(j) of the M.P.E.P. states that to establish a *prima facie* case of obviousness, three basic criteria must be met:

- (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine the reference teachings;
- (2) there must be a reasonable expectation of success; and
- (3) the prior art reference must teach or suggest all of the claim limitations.

Applicants submit that Patel and Campbell fail to teach or suggest all of the limitations recited in the rejected claims. Each of claims 39, 42, 44, and 50 depends from claim 36 and, therefore, contains all of the limitations of claim 36. Patel fails to teach or suggest the claim limitations "channels" and "transport of fluid between a medical treatment site and a remote area" for at least all of the reasons provided above in connection with the patentability of claim 36 over Patel.

The rejection of claims 39, 42, 44, and 50 under 35 USC § 103(a) as being unpatentable over Patel is improper and should be withdrawn.

Each of claims 59 and 60 depends from claim 51 and, therefore, contains all of the limitations of claim 51. Patel and Campbell fail to teach or suggest the claim limitations "channels" and "transport fluid between a medical treatment site and a remote area" for at least all of the reasons provided above in connection with the patentability of claim 51 over each of Patel and Campbell.

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In summary, the rejections of claims 39, 42, 44, 50, 59 and 60 under 35 USC § 103(a) as being unpatentable over either Patel or Campbell are improper and should be withdrawn.

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Conclusion

In view of the above, Applicants submit that the application is in condition for allowance.  
Reconsideration of the application and allowance of claims 36-60 is requested.

Respectfully submitted,

Date

10/13/2004

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